

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENT
(Chapter II of the Patent Cooperation Treaty)

REC'D 24 FEB 2005
WIPO PCT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference W1460-000000	<div style="display: flex; justify-content: space-between;"> FOR FURTHER ACTION See Form PCT/IPEA/416 </div>	
International application No. PCT/JP 2004/004554	International filing date (day/month/year) 30.03.2004	Priority date (day/month/year) 31.03.2003
International Patent Classification (IPC) or national classification and IPC Int.Cl. C07D239/84, A61K31/517, A61P25/28, 25/20, 25/22, 25/24, 3/04, 9/12, 9/00, 25/16, 25/08, 3/00		
Applicant TAISHO PHARMACEUTICAL CO., LTD		

1.	This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2.	This REPORT consists of a total of <u>7</u> sheets, including this cover sheet.
3.	This report is also accompanied by ANNEXES, comprising: <div style="margin-left: 20px;"> a. <input type="checkbox"/> a total of _____ sheets, as follows: <div style="margin-left: 20px;"> <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. </div> </div> <div style="margin-left: 20px;"> b. <input type="checkbox"/> a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions). </div>
4.	This report contains indications relating to the following items: <div style="margin-left: 20px;"> <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input checked="" type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input checked="" type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application </div>

Date of submission of the demand 13.08.2004	Date of completion of this report 09.02.2005	
Name and mailing address of the IPEA/JP Japan Patent Office 3-4-3, Kasumigaseki, Chiyoda-ku, Tokyo 100-8915, Japan	Authorized officer KOJI ITO Telephone No. +81-3-3581-1101 Ext. 3452	<div style="border: 1px solid black; padding: 2px;">4C</div> <div style="border: 1px solid black; padding: 2px;">9450</div>

Form PCT/IPEA/409 (cover sheet) (January 2004)

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP 2004 / 004554

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ the international application as originally filed/furnished
- ☐ the description:
pages _____ as originally filed/furnished
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____
- ☐ the claims:
pages _____ as originally filed/furnished
pages* _____ as amended (together with any statement) under Article 19
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____
- ☐ the drawings:
pages _____ as originally filed/furnished
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (specify): _____
- ☐ any table(s) related to sequence listing (specify): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (specify): _____
- ☐ any table(s) related to sequence listing (specify): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/004554

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 49-51

because:

☒ the said international application, or the said claims Nos. 49-51
relate to the following subject matter which does not require an international preliminary examination (*specify*):

Claims 49-51 pertain to a method for treatment of the human body by therapy.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 49-51

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the
Administrative Instructions in that:

the written form

☐

has not been furnished

☐

does not comply with the standard

the computer readable form

☐

has not been furnished

☐

does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing do not comply with the technical requirements provided
for in Annex C-bis of the Administrative Instructions in that the computer readable form:

☐

has not been furnished

☐

does not comply with the technical requirements

☐ See Supplemental Box for further details.

Box No. IV Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
☐ paid additional fees.
☐ paid additional fees under protest.
☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:

- ☐ complied with.
☒ not complied with for the following reasons:

Formula (I), Q-L-Y-R1, in claim 1 involves a great number of compounds. However, the common structure among those compounds does not appear to be a significant structural element.

Therefore, the inventions related to compounds are not deemed to form a single general inventive concept.

4. Consequently, this report has been established in respect of the following parts of the international application:

- ☒ all parts.
☐ the parts relating to claims Nos. _____

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2004/004554

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims		YES
	Claims	<u>1-48, 52-57</u>	NO
Inventive step (IS)	Claims		YES
	Claims	<u>1-48, 52-57</u>	NO
Industrial applicability (IA)	Claims	<u>1-48, 52-57</u>	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Formula (I), Q-L-Y-R1, in claim 1 consists of 4 parts which vary immensely and involves a great number of compounds so that complete search is unable to be done.

Document A : WO 97/20823 A2 (NOVARTIS AZ) 1997.06.12

The subject matter of Claims 1-4, 52-57 appear neither to be novel nor to involve an inventive step.

Document A shows compounds of formula (I) which is useful for treatment of disorder or disease state caused by eating disorder, memory loss; depression, anxiety and so on. Those compounds overlap compounds of Formula (I) in this application.

Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

<u>Application No. Patent No.</u>	<u>Publication date (day/month/year)</u>	<u>Filing date (day/month/year)</u>	<u>Priority date (valid claim) (day/month/year)</u>
WO 03/028641 A2 (TAISHO PHARMACEUTICAL CO., LTD) [E, X]	10.04.2003	30.09.2002	01.10.2001

2. Non-written disclosures (Rule 70.9)

<u>Kind of non-written disclosure</u>	<u>Date of non-written disclosure (day/month/year)</u>	<u>Date of written disclosure referring to non-written disclosure (day/month/year)</u>
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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Formula (I) in claims involves a great number of compounds. However, only parts of the claimed compounds are disclosed in the meaning as described in PCT Article 5 and thus it is recognised that the claims which relate to Formula (I) is not supported by the disclosure in the description in the meaning in PCT Article 6.

Claim 1 is neither clear nor concise.